Internet Interventions xxx (xxxx) xxx–xxx

Contents lists available at ScienceDirect

Internet Interventions

journal homepage: www.elsevier.com/locate/invent

Using internet-based self-help to bridge waiting time for face-to-face outpatient treatment for Bulimia Nervosa, Binge Eating Disorder and related disorders: Study protocol of a randomized controlled trial

Bianka Vollert[a,*], Ina Beintner[a], Peter Musiat[b], Gemma Gordon[b], Dennis Görlich[c], Barbara Nacke[a], Juliane Schmidt-Hantke[a], Rachel Potterton[b], Lucy Spencer[b], Nina Grant[d], Ulrike Schmidt[b], Corinna Jacobi[a]

[a] Technische Universität Dresden, Institut für Klinische Psychologie und Psychotherapie, Chemnitzer Str. 46, D-01187 Dresden, Germany
[b] King's College London, Institute of Psychiatry, Psychology and Neuroscience, Box P059, De Crespigny Park, London SE5 8AF, UK
[c] Westfälische Wilhelms-Universität Münster, Institute of Biostatistics and Clinical Research, Schmeddingstraße 56, Münster, Germany
[d] South London and Maudsley NHS Foundation Trust, Eating Disorders Outpatient Unit, The Maudsley Hospital, Denmark Hill, London SE5 8AF, UK

ARTICLE INFO

Keywords:
Eating disorders
Internet-based interventions
Guided self-help
Bridging waiting time
Outpatients
Randomized controlled trial

ABSTRACT

Background: Eating disorders are serious conditions associated with an impaired health-related quality of life and increased healthcare utilization and costs. Despite the existence of evidence-based treatments, access to treatment is often delayed due to insufficient health care resources. Internet-based self-help interventions may have the potential to successfully bridge waiting time for face-to-face outpatient treatment and, thus, contribute to overcoming treatment gaps. However, little is known about the feasibility of implementing such interventions into routine healthcare. The aim of this study is to analyze the effects and feasibility of an Internet-based self-help intervention (everyBody Plus) specifically designed for patients with Bulimia Nervosa, Binge Eating Disorder and other specified feeding and eating disorders (OSFED) on a waiting list for outpatient face-to-face treatment. The aim of this paper is to describe the study protocol.

Methods: A multi-country randomized controlled trial will be conducted in Germany and the UK. N = 275 female patients awaiting outpatient treatment will be randomly allocated either to the guided online self-help intervention "everyBody Plus" or a waitlist control group condition without access to the intervention. everyBody Plus comprises eight weekly sessions that cover topics related to eating and exercise patterns, coping with negative emotions and stress as well as improving body image. Participants will receive weekly individualized feedback based on their self-monitoring and journal entries. Assessments will take place at baseline, post-intervention as well as at 6- and 12-months follow up. In addition, all participants will be asked to monitor core eating disorder symptoms weekly to provide data on the primary outcome. The primary outcome will be number of weeks after randomization until a patient achieves a clinically relevant improvement in core symptoms (BMI, binge eating, compensatory behaviors) for the first time. Secondary outcomes include frequency of core symptoms and eating disorder related attitudes and behaviors, as well as associated psychopathology. Additional secondary outcomes will be the participating therapists' confidence in treating eating disorders as well as perceived benefits of everyBody Plus for patients.

Discussion: To the best of our knowledge, this is the first randomized controlled trial examining the effects of Internet-based self-help for outpatients with eating disorders awaiting face-to-face outpatient treatment. If proven to be effective and successfully implemented, Internet-based self-help programs might be used as a first step of treatment within a stepped-care approach, thus reducing burden and cost for both patients and health care providers.

* Corresponding author.
E-mail addresses: Bianka.Vollert@tu-dresden.de (B. Vollert), Ina.Beintner@tu-dresden.de (I. Beintner), peter.musiat@kcl.ac.uk (P. Musiat), gemma.gordon@kcl.ac.uk (G. Gordon), dennis.goerlich@ukmuenster.de (D. Görlich), Barbara.Nacke@tu-dresden.de (B. Nacke), Juliane.Schmidt-Hantke@tu-dresden.de (J. Schmidt-Hantke), rachel.h.potterton@kcl.ac.uk (R. Potterton), lucy.spencer@kcl.ac.uk (L. Spencer), nina.grant@slam.nhs.uk (N. Grant), ulrike.schmidt@kcl.ac.uk (U. Schmidt), Corinna.Jacobi@tu-dresden.de (C. Jacobi).

https://doi.org/10.1016/j.invent.2018.02.010
Received 20 December 2017; Accepted 19 February 2018

1. Introduction

Patients with eating disorders (EDs) have significantly impaired health-related quality of life and EDs are associated with increased healthcare utilization and healthcare costs (Ágh et al., 2015; Agras, 2001). The impairment is particularly high in patients with binge eating/purging behavior (DeJong et al., 2013).

Systematic reviews and treatment guidelines have repeatedly recommended cognitive-behavior therapy (CBT) as the first choice of treatment for Bulimia Nervosa (BN) and Binge Eating Disorder (BED) (Mitchell et al., 2007; National Institute for Health and Care Excellence (NICE), 2017; Vocks et al., 2010; Wilson and Shafran, 2005). However, access to treatment is often limited or delayed. Apart from barriers in the help-seeking process on the side of the patient [e.g., fear of stigmatization, poor treatment motivation or lack of knowledge regarding the ED (Becker et al., 2010; Evans et al., 2011)], mental health care delivery in many countries is characterized by a gap between demand and availability of evidence-based treatments (Knapp et al., 2007; Kohn et al., 2004). Moreover, even when people with mental health disorders (e.g., eating disorders) decide to seek professional help, they often do not receive prompt support due to limited face-to-face treatment capacities and long waiting periods. In Germany, for example, more than every fourth adult is affected by one or more mental health disorders (Jacobi et al., 2014); the number of licensed psychotherapists however, is not sufficient to meet this demand (BPtK, 2011). A report from the German Psychotherapists' Association ("Bundespsychotherapeutenkammer") showed that people seeking outpatient treatment have to face on average a three-month waiting period until an initial meeting can be scheduled (BPtK, 2011) and even more time elapses until the first treatment session takes place.

In the UK, the picture is similar. It is estimated that only a quarter of people with a mental health disorder receive any treatment at all (The Centre for Economic Performance's Mental Health Policy Group, 2012). Of these, only 10% receive evidence-based psychological therapies. Over half of the people affected by mental health problems wait more than three months until treatment is started – and one tenth has to wait for more than a year (Mind, 2013). The UK mental health charity Mind recommends that waiting time should not exceed a maximum of four weeks (Mind, 2013) as shorter waiting periods are associated with greater treatment satisfaction (Mind, 2010).

For patients with eating disorders, barriers to treatment are particularly high as some therapists decline treating these patients (Burket and Schramm, 1995). The rather poor long-term outcome (Steinhausen and Weber, 2009), the associated physical and comorbid conditions and patients` ambivalence towards treatment can result in therapists feeling poorly equipped to take on these patients and discourage them from providing treatment at all (Burket and Schramm, 1995). Evidence from epidemiological studies shows that only a small proportion of patients (6%) suffering from Bulimia Nervosa receive psychological treatment (Hoek, 2006). Given the seriousness of the disorders and the associated burden and costs (Ágh et al., 2015; Agras, 2001), providing people with EDs with adequate interventions as early as possible is of crucial importance.

However, some researchers suggest that limited resources will always be a problem in most health care systems, even if the number of trained specialists is scaled up (Fairburn and Patel, 2014). Accordingly, alternative ways of providing psychological treatments have to be designed and implemented to lower current barriers to care. Self-help interventions may help to facilitate immediate access to metal health care, thus bridging the treatment gap for patients with BN and BED (Beintner et al., 2014). Several studies have shown that a considerable proportion of patients (9–64%, median 30%) with BN and BED achieve abstinence from binge eating after 8–12 weeks only by participating in a CBT-based (online or offline) self-help program (Beintner et al., 2014), with guided self-help programs showing better effects than unguided programs (Beintner et al., 2014). As part of a stepped care approach, current treatment guidelines for BN and BED, recommend participating in a self-help program as a first step of treatment (National Institute for Health and Care Excellence (NICE), 2017). Using a CBT-based self-help program as the first step in treatment of BN was more effective in terms of reducing ED-related psychopathology (frequency of binge eating and compensatory behaviors) (Mitchell et al., 2011) and more cost-effective (Crow et al., 2013) in comparison with conventional CBT as a first step in treatment. Hence, delivering self-help interventions at an early stage at a first step of treatment may also be a promising strategy to manage limited resources for outpatient treatment (Crow et al., 2013).

In recent years, self-help interventions have increasingly been offered online. To date, the effects of Internet-based interventions as a stand-alone treatment for BN and BED have only been evaluated in a small number of trials (Aardoom et al., 2016a; Carrard et al., 2011a,c; Ruwaard et al., 2013; Sanchez-Ortiz et al., 2011; ter Huurne et al., 2015) and considered in recent systematic reviews with mainly promising results (Aardoom et al., 2013, 2016b; Bauer and Moessner, 2013; Dolemeyer et al., 2013; Le et al., 2017; Loucas et al., 2014; Melioli et al., 2016; Schlegl et al., 2015). In general, compared with waiting list controls, Internet-based interventions proved to be more effective in reducing global ED pathology (including the frequency of binge eating and compensatory behaviors) and were associated with a greater improvement of ED related quality of life (Aardoom et al., 2013). Online self-help has also been shown to contribute to motivation for change (d = 0,52–0,87), even if the focus is not mainly on ED symptoms (Hötzel et al., 2014). Nevertheless, evidence from randomized controlled trials on the impact of Internet-based self-help interventions in routine care settings (e.g., outpatient or inpatient treatment centers) is limited, especially when used to bridge waiting time for psychotherapy.

However, using online self-help interventions to bridge waiting time for outpatient face-to-face psychotherapy could have several advantages: Patients can receive some basic psychoeducational information on EDs online, which saves time that can be used to address other problems (e.g., interpersonal, emotional problems, comorbidities) during subsequent face-to-face treatment. Participation in an online guided self-help program instead of simply waiting for face-to-face treatment could also facilitate the motivation for change and keep this motivation active during the waiting period. Overall, participation in an online self-help intervention during the waiting period may have the potential to reduce ED symptoms (or to prevent ED symptom progression) and to better prepare the patient for subsequent treatment. This could – at best – result in a more rapid improvement of ED core symptoms and fewer face-to-face sessions subsequently needed or even make a subsequent face-to-face treatment unnecessary, thus, also providing a potentially more cost-effective alternative to face-to-face treatment.

In the field of eating disorders, to our knowledge, no trial has been conducted in which an online self-help intervention was offered with the aim of bridging waiting times. Preliminary evidence on the effects of such interventions comes from non-randomized controlled trials. Carrard et al. (2011b) offered a guided self-help online BED program to obese patients with BED on a waiting list for a weight loss treatment program. The study was not specifically designed to bridge waiting time, but participants were recruited from an existing waiting list and the intervention was offered during their 6-month waiting period. Around half of the patients (55%) invited to take part in the online program chose to participate instead of waiting. Their data were compared with data from patients who waited for their treatment without receiving the opportunity to participate in the online program. At post-intervention, a higher percentage of patients in the self-help condition reported abstinence from binge eating compared with patients in the control condition (45 vs. 15%; N = 42). Positive effects were also found for disordered eating attitudes (e.g., EDE-Q weight and shape concerns) and quality of life (Carrard et al., 2011b). These effects were

maintained until 6 months follow-up, after all BED patients had taken part in the weight loss treatment program they had registered for.

In addition, only two randomized controlled trials have been published for other mental health disorders, i.e., depression and anxiety disorders (Kenter et al., 2016; Kok et al., 2014). In the first study, an Internet-based problem solving treatment produced comparable outcomes in patients with major depression to the use of an unguided self-help book while waiting for treatment (Kenter et al., 2016). In the second study, participation in an Internet-based program for phobias was associated with a significantly greater reduction in phobic and depressive symptoms at 5 weeks posttest, compared to a waiting list control group receiving a self-help book only (Kok et al., 2014).

Taken together, there is limited evidence on the use and effects of Internet-based interventions to bridge waiting time for face-to-face treatment for mental disorders, although results of the few available studies show some promise. Although effective as stand-alone interventions, online self-help interventions may have different effects when being offered to outpatients awaiting face-to-face treatment. The aim of our study, therefore, is to assess the effects of an Internet-based intervention designed to bridge waiting time for outpatient face-to-face treatment for BN, BED and other specified feeding and eating disorders (OSFED). The current study is the first study to offer an online intervention for patients with an ED during the waiting period for outpatient treatment, and evaluate its effects compared with the effects of outpatient treatment only. As patients will be enrolled in regular face-to-face treatment afterwards, it is unclear how this might influence their motivation to use the program and adhere to it.

2. Materials and methods

2.1. Objectives and hypotheses

Self-help interventions could have the potential to bridge the treatment gap for BN and BED and could represent a first step in a stepped-care approach. However, they have hardly been implemented in routine mental health care settings (e.g., private practices, outpatient centers). To address this shortcoming, we aim to evaluate the effects of a guided Internet-based self-help program (everyBody Plus) for female patients with BN, BED and OSFED awaiting outpatient treatment. We expect the included everyBody Plus intervention to be associated with both a more rapid reduction of core eating disorder symptoms and higher abstinence rates compared with the control condition who remain on the waiting list and do not receive the intervention.

2.2. Participants and recruitment

We will include women aged 18 and above who seek outpatient face-to-face treatment for Bulimia Nervosa (BN), Binge Eating Disorder (BED) or other specified feeding and eating disorders (OSFED) according to DSM5 (American Psychiatric Association, 2013). Although it is increasingly recognized that men, too, develop eating disorders, interventions for men need to consider the rather different symptom patterns and manifestations of ED in males (Calzo et al., 2016). Due to the time and financial constraints of this study, this was not possible here. An adaption of the intervention for men may be created in the future. Eligible patients need to have access to the internet and give informed consent to participation in the study.

We will exclude (i) patients with a BMI $< 18.5\,kg/m^2$, (ii) patients in need for inpatient eating disorder treatment due to the severity of the disorder, (iii) patients with significant psychiatric comorbidity needing treatment in its own right (e.g., substance dependence, major psychiatric disorders or acutely suicidal tendency), (iv) patients on antidepressant medication who have not been on a stable dose for at least four weeks. Also, patients will be excluded if they are not eligible for treatment coverage by health insurances or the NHS due to low symptom severity, based on the judgement of the cooperating therapist or researcher of this study.

2.2.1. Recruitment in Germany

In Germany, we will recruit participants via cooperating psychotherapists in private practices and outpatient treatment centers as well as psychotherapy training institutions. Psychotherapists (clinical psychologists, psychiatrists, GPs with additional qualification in psychosomatics) are eligible for cooperation if they are licensed to conduct Cognitive Behavioral Therapy (CBT) or Psychodynamic Therapy (PDT) in Germany or are in supervised training to be licensed, keep a waiting list for their practice or institution (i.e., see patients for one diagnostic session and cue them up for the next upcoming timeslot) and are willing to treat women with eating disorders. Cooperating therapists and outpatient treatment centers are recruited via mailings, phone calls and (print and e-mail) announcements through professional organizations as well as an advertisement in the journal of the German clinical psychologists' association (Bundespsychotherapeutenkammer), which is received by every licensed clinical psychologist in Germany.

In addition, we will implement a second recruitment strategy by directly approaching women with BN, BED or OSFED without the involvement of a licensed psychotherapist. Within this recruitment procedure, interested women awaiting outpatient treatment are able to refer themselves to the study. Potential participants will be informed about the opportunity to take part in the study via flyer and other information materials in counselling centers, self-help groups, (online) help-seeking forums and websites dealing with eating disorders. To be considered for participation, it is necessary that a certified physician or psychotherapist confirm their eating disorder symptomatology and other study-relevant symptoms (i.e., inclusion and exclusion criteria). Following this confirmation, the study team will decide if the woman is eligible to participate in the study.

2.2.2. Recruitment in the UK

In the UK, we will recruit participants from multiple sources. The South London and Maudsley NHS Foundation Trust is a confirmed recruitment site. This hospital trust has a large catchment area and offers healthcare services to approximately 2 million people. Additional hospital trusts can view the UK study on the National Institute for Health Research Clinical Research Network (NIHR CRN) Portfolio database and apply to become recruitment sites. Additional participants will be recruited via the KCL website and the KCL staff and student medical center. Advertising through the national ED charity Beat will allow generate UK-wide interest in the study. Furthermore, the study will be advertised in university email circulars sent by administrators to the student population of UK universities.

2.3. Study design and randomization

This study is a pragmatic multi-country, multicenter, randomized controlled trial with 2 parallel conditions (everyBody Plus vs. waiting list control condition), conducted in Germany and the UK. Core ED symptoms (BMI, binge eating, compensatory behaviors) will be assessed weekly during a 52 week period. In addition, secondary outcomes will be assessed at pre- and post-intervention as well as 6- and 12-months-follow-up (see Fig. 1).

At the end of their initial diagnostic session, patients who are put on a waiting list and cannot start treatment immediately will receive written information about the study along with an access code for the program website that identifies the therapist who referred them. In the case of self-referred participants, the access code will be given directly to participants by the study team. Entering the access code is obligatory for the registration in the online program. The patients will subsequently receive detailed written information about the study on the program website and be able to give informed consent. Participants are reminded that that the online program is offered specifically to women with BN, BED or OSFED who may be on a waiting list for face-to-face

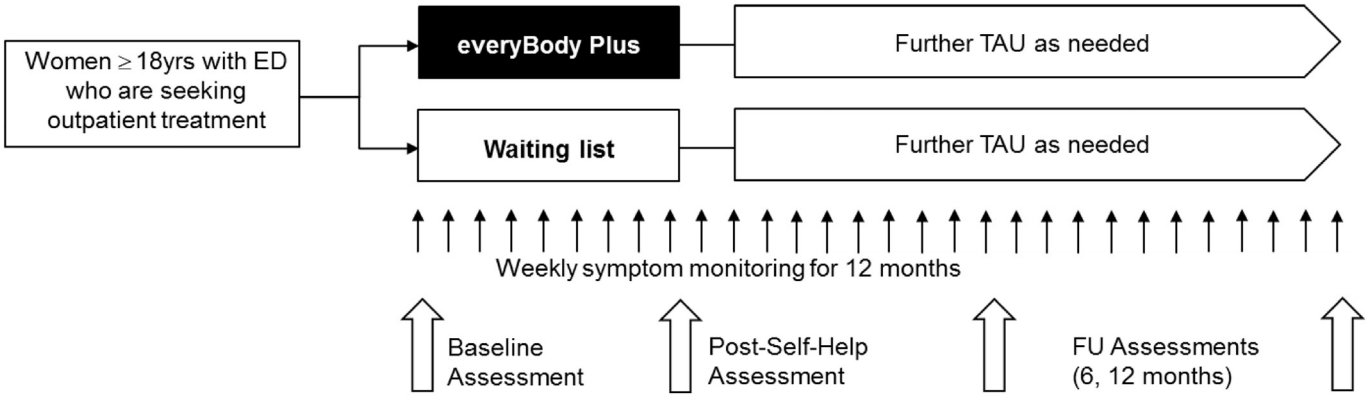

Fig. 1. Study design.

outpatient therapy and that participation in the program is not meant as substitute for psychotherapy but could be used to bridge waiting time with beneficial effect. After the sign-up process and completion of a baseline assessment, patients will be randomly allocated to either everyBody Plus or the waiting list control condition on the basis of a computer-generated randomized number list. After randomization, women in the everyBody Plus group will receive access to the online self-help intervention in addition to being prompted to monitor their symptoms weekly, while women in the waiting list condition will only be prompted to monitor their symptoms weekly. Women will take up regular outpatient psychotherapy sessions whenever a timeslot becomes available. Weekly symptom monitoring continues until 12 months (52 weeks) past randomization. Secondary outcomes will be assessed at post-intervention and FU assessments (6 and 12 months past randomization). In addition, cooperating therapists in Germany will be asked to provide information on the number and dates of sessions conducted with participating patients and an evaluation of current ED specific symptomatology quarterly (once the participant starts regular outpatient treatment).

In the UK, a minority of participants will be recruited through advertisements and word-of-mouth, and thus will not be screened for the study by their NHS health care provider. The eligibility of these participants will be assessed over the phone by a trained researcher of the KCL team, under the supervision of a psychiatrist, and in accordance with the specific inclusion and exclusion study criteria. For participants who are referred to the study through an NHS service provider data on treatment attendance will be obtained from the hospital trust's electronic patient monitoring system. Participants recruited outside of NHS sites will be asked to provide information on attending face-to-face treatment through the weekly symptom diary and the post-intervention and follow-up assessments.

Patients can collect points for each timely completed weekly symptom checklist and baseline/post-intervention/FU-assessment. They can redeem these points for money or vouchers after 12 months (after FU12 assessment). Cooperating therapists in Germany will receive an expense allowance for the additional effort of providing information on treatment dose and current symptomatology (25€ per quarter per trial patient in treatment).

The trial is registered at http://www.isrctn.org, number ISRCTN12608780. Ethics approval has been obtained by the ethics committee of TU Dresden (EK 84032016) and both King's College London and the NHS (North West – Greater Manchester East Research Ethics Committee reference number 16 /NW/0888). The trial will be conducted in compliance with the protocol, the Declaration of Helsinki and good clinical practice. All relevant EU legislation and international texts on privacy will be observed and respected.

2.4. Intervention

everyBody Plus is an eight-week online self-help program based on ED specific cognitive behavioral therapy for women who binge eat. The main focus is on reducing and/or preventing binge eating by implementing alterative behavioral strategies into daily life. In line with this, everyBody Plus aims to do the following: (i) to communicate a positive body image, (ii) to support the development and maintenance of balanced eating, (iii) to teach alternative behavioral strategies in situations where unhelpful eating behaviors occur, (iv) to enhance self-confidence independently of weight and body shape.

The program consists of eight weekly sessions and includes reading assignments, a weekly symptom checklist assessing the number of binges and compensatory behaviors per week, a personal journal and behavioral exercises. Topics covered are the development and maintenance of eating disorders, balanced eating and exercise patterns, dealing with “forbidden foods” and binge eating/purging, improving body image, coping with stress and negative emotions, perfectionism and self-esteem. everyBody Plus was designed to target psychological conditions of BN and BED (binge eating), without directly addressing weight loss and weight management. Patients will receive weekly personal feedback based on their self-monitoring and journal entries.

The program is supplemented by a moderated asynchronous discussion board to exchange experiences and thoughts with other patients. Trained clinical psychologists or certified psychologists with a master's degree supervised by a psychotherapist licensed to conduct CBT will provide personal feedback and moderate the online discussion board. everyBody Plus program moderators attended a training workshop where they learned about the specific philosophy of the intervention and received detailed instructions on intervention delivery. The Internet-based and therefore site-independent intervention is guided by staff at TU Dresden (German version) and KCL (English version). Cooperating therapists in Germany will not be involved in the self-help intervention. Nominated therapists in participating eating disorder units in the UK will be trained in providing online support to participants at a half-day workshop hosted by study researchers. At the end of each session, participants will be asked to give brief feedback on how helpful they found the session.

An earlier version of the program [StudentBodies+ (German version) and StudentBodies-Eating Disorders (English version)] has previously been shown to be effective in reducing ED symptoms in RCTs of young women with subthreshold eating disorders (Jacobi et al., 2012; Saekow et al., 2015). Within the present RCT, the program is used in women with full syndrome eating disorders (BN, BED, OSFED) awaiting outpatient face-to-face treatment. For this purpose, the StudentBodies Plus program was revised and adapted to the specific target group of women with eating disorders with binge eating behavior and migrated into a new online platform. Mainly, we updated the layout of the program, replaced long text passages by explanatory videos and included

written and audio testimonials of fictitious participants. Although it is expected that many participants will proceed to regular outpatient therapy afterwards, we emphasize the benefits of working with everyBody Plus, to increase the participants' motivation to adhere to and complete the intervention. Also, we implemented a weekly symptom checklist to allow monitoring of ED core symptoms and provision of the primary outcome. The name of the program was changed to everyBody Plus in order to show that the program is applicable to women of all ages and not just students. A responsive web-design allows patients to access the intervention though the Internet, a mobile phone or a tablet.

2.4.1. Control condition

Patients allocated to the waiting list control condition will only be prompted to complete the weekly self-monitoring of core ED symptoms. They will neither receive access to the program nor receive feedback on their entries in the symptom checklist. In case of problems with using the platform, participants will receive technical support from the everyBody Plus team. The benefits of monitoring eating disorder symptoms (systematically monitoring eating habits, recognizing progress and changes, being aware of periods with unhelpful eating behaviors) are emphasized, to keep participants in the control group engaged with the study.

2.5. Assessment and data management

Assessments will be conducted before randomization (baseline, T1), at the end of the intervention (8 weeks past randomization, T2) as well as at 6- (T3) and 12-month-follow up (T4). A short intermediate assessment will take place 4 weeks past randomization. All questionnaires are given online. Participants will benefit from being awarded points for each completed assessment, which they are able to redeem for cash or a voucher upon completion of the study.

Table 1 gives an overview of instruments that will be used at each of the four main assessment points. Additional measures addressing potential moderator and mediator variables are included (see Secondary outcomes section).

All study data will be collected on the Minddistrict platform. Data management and monitoring will be provided by Westfälische Wilhelms-Universität Münster for the whole ICare consortium in order to maintain a comparably high quality in the conduct of the ICare research projects. Study data are monitored for completeness, timeliness and interval validity. The processing of a personal data plan is protected by appropriate technical and organizational measures. Personal data will be pseudonymized and any data transfer will be encrypted, e.g. by SSL secured HTTPS connection. After the end of the trial, data will be anonymized for further analysis. Only aggregated data will be presented in any publication resulting from the study.

2.6. Outcomes

2.6.1. Primary outcome

The primary outcome is the number of weeks after randomization until a patient achieves a clinically relevant improvement in core symptoms for the first time. Clinically relevant improvement is defined as abstinence from binge eating and compensatory behaviors and a BMI $> 18.5\,kg/m^2$ over a period of at least four weeks. To assess the primary outcome, each participant will be asked to monitor the presence and frequency of eating disorder symptoms (binge eating and compensatory behaviors) in a weekly symptom checklist. The checklist contains eight questions assessing the frequency of binge eating and compensatory behavior. These frequencies are measured as numeric variables.

2.6.2. Secondary outcomes

Secondary outcomes include standard ED measures as well as measures assessing associated psychopathology. The Eating Disorder Examination Questionnaire [EDE-Q (Fairburn and Beglin, 2008; Hilbert and Tuschen-Caffier, 2006)] will be used to assess ED psychopathology. Also, frequencies of core ED symptoms (i.e., binge eating, compensatory behaviors) in the previous month will be assessed. The five-item Weight Concerns Scale [WCS (Grund, 2003; Killen et al., 1996)] will be used to assess concerns with weight as associated to body image. Fruit and vegetable consumption in the last seven days will be assessed by four questions asking about the intake of fruit, vegetable, smoothies and juices. To assess whether participants take their meals depending on physical cues of hunger and satiety, the Intuitive Eating Scale [IES (Herbert et al., 2013; Tylka, 2006)] will be used. BMI will be calculated via self-reported weight and height.

As secondary outcome measures of associated psychopathology, we will use the Patient Health Questionnaire 9 [PHQ-9 (Löwe et al., 2004)] assessing depression, the Generalized Anxiety Disorder 7 [GAD-7 (Spitzer et al., 2006)] assessing anxiety and the Alcohol Use Disorders Identification Test-Consumption [AUDIT-C (Bush et al., 1998; Wurst et al., 2013)] assessing alcohol consumption. For the assessment of quality of life, we will use the Assessment of Quality of Life-8D [AQoL-8D (Richardson et al., 2014)]. The Rosenberg Self-Esteem Scale [RSE (Ferring and Filipp, 1996; Rosenberg, 1965)] will be used to measure self-esteem. For health-economic analyses, the Client Service Receipt Inventory [CSRI (Beecham and Knapp, 2001)] will be administered at each of the four main assessment points. This allows frequency of service contacts to be recorded in a manner commensurate with estimating the costs of treatment.

Within the trial, we will also assess potential moderators and mediators of adherence and outcome. Potential moderator variables (e.g., sociodemographic variables, participants' expectations and intention to use the program) will be assessed prior to randomization. Potential mediator variables (e.g., change in psychopathology,

Table 1
Measures and time points of assessment.

Measures		Baseline	Post intervention (week 8)	FU 6 months	FU 12 months
ED core symptoms	Binge eating and compensatory behavior	x	x	x	x
EDE-Q	Eating disorder psychopathology	x	x	x	x
WCS	Weight and shape concerns	x	x	x	x
IES	Intuitive eating tendencies	x	x	x	x
PHQ-9	Symptoms of depression	x	x	x	x
GAD-7	Symptoms of anxiety	x	x	x	x
AUDIT-C	Alcohol consumption	x	x	x	x
AQoL-8D	Quality of life	x	x	x	x
RSE	Self-esteem	x	x	x	x
CSRI	Economic evaluation	x	x	x	x

EDE-Q Eating Disorder Examination-Questionnaire, WCS Weight Concerns Scale, IES Intuitive Eating Scale, PHQ-9 Patient Health Questionnaire 9, GAD-7 Generalized Anxiety Disorder 7, AUDIT-C Alcohol Use Disorders Identification Test-Consumption, AQoL-8D Assessment of Quality of Life-8D, RSE Rosenberg Self-Esteem Scale, CSRI Client Service Receipt Inventory, FU Follow up.

satisfaction with treatment) will be assessed once during the intervention (four weeks post randomization). Also, the therapeutic alliance will be assessed using the Working Alliance Inventory – short revised [WAI-SR (Hatcher and Gillaspy, 2006; Wilmers et al., 2008); intervention group only]. Expectations towards the everyBody Plus intervention will be assessed at pre- and mid-intervention using the "Stundenbogen für die Allgemeine und Differentielle Einzel-Psychotherapie" [STEP (Krampen, 2002); patient version modified for online interventions]. Adherence to the intervention (e.g., the number of completed sessions, completed diary entries or messages written in the discussion board), will be tracked automatically through the online intervention platform.

In addition, participating therapists' confidence in treating eating disorders (self-report on relevant therapeutic skills and emotions while treating patients with Eating Disorders) will be assessed and therapists' perceived benefits of everyBody Plus for patients will be measured using the "Stundenbogen für die Allgemeine und Differentielle Einzel-Psychotherapie" [STEP (Krampen, 2002); therapist version modified for online interventions]. NHS therapists in the UK will complete the English version of the STEP (Krampen, 2002). Also, cooperating therapists will be asked once per quarter to provide information about the number of therapy session utilized by the participant.

2.7. Statistical methods

The statistical analysis of the primary and secondary outcomes follows adopted guidelines, e.g. ICH E9 and will be described in more detail in a statistical analysis plan (SAP). Before final data analysis, a blinded data review step will be performed, to inform decisions on the imputation strategy and selection of potential covariates in multivariable model. Overall, the analysis strategy for this trial consists of four steps: (i) data description, (ii) analysis of the primary hypothesis including sensitivity analyses, (iii) secondary analyses, and (iv) further exploratory analyses.

The balancing of participant randomization will be checked by appropriate statistical tests on the baseline variables. Furthermore, the study collective will be characterized by descriptive statistical methods. Absolute and relative frequencies will be used for categorical variables, means, median, standard deviations and inter quartile range will be used for continuous variables. Additionally, suitable graphics will be used to display the data, such as histograms, boxplots and bar charts. Means and medians will be supplemented by 95% confidence intervals (CI). All measurement time points will be described separately. Also, descriptive statistics will be provided for both study arms. Assumptions about the statistical distribution of measured variables will be tested using appropriate test. Normality will be assessed by histograms, kurtosis and the Kolmogorov-Smirnov test.

2.7.1. Primary confirmatory analysis

The primary hypothesis of the trial tests if participants benefit from the online program compared to a waiting list condition. The effect of the program is tested using a time-to-event endpoint. For the primary outcome, time to clinically relevant improvement of ED symptoms, the two arms everyBody Plus-self-help and waiting list control condition will be compared using a two-sided log rank test. The primary analysis will be performed on the full analysis set of patients who provided data at baseline (ITT principle). The primary analysis will be performed on a multiple significance level of 5% within a 2-stage adaptive design planned for this trial. An interim analysis is planned after 39 events have been observed. The purpose of the interim analysis is mainly to recalculate the sample size.

The results of the trial will be reported according to the CONSORT 2010 Statement (Eysenbach and Consort-Ehealth Group, 2011; Moher et al., 2001, 2010).

2.7.2. Sensitivity analyses

After the final analysis, sensitivity analyses on the primary analysis will be performed using the per-protocol (PP) collective. Furthermore, we will fit a Cox-proportional model including variables preselected in the blinded review of the data. Baseline variables that qualify as potential confounders will also be considered for this sensitivity analysis. Additionally, a stratified analysis by country (Germany, UK) and within strata (subgroup analysis) will be performed.

2.7.3. Secondary analyses

Analyses of the secondary outcomes at individual time points will be made by either using Student's *t*-Test for unpaired data or Mann-Whitney *U* test, depending on normal distribution of scores. Categorical variables will be analyzed using Fisher's Exact Test or Chi-Squared tests. Additionally, primary and secondary outcomes will be analyzed using multilevel mixed effect models (MMEM) and multivariable Cox proportional hazard models. Separate MMEM models will be calculated for each secondary outcome variable. Depending on the distribution of data, we will choose linear models (for normally distributed data) or negative binomial models (for left-skewed data). Each model includes assessment time as a predictor. Further covariates will be entered as necessary, e.g. baseline characteristics of participants, or variables associated with dropout, to control for confounding. We will perform a competing risk analysis of the primary endpoint to assess the effects of simultaneously occurring events, such as start of face-to-face therapy.

Missing data in secondary analyses will be handled using Full-information-maximum likelihood estimation. We will consistently use the nominal significance level of 0.05 (two-tailed).

2.7.4. Moderator and mediator analyses

Moderator and mediator analyses will be conducted within a separate work package of the ICare project.

2.7.5. Cost-effectiveness analyses

Cost-effectiveness analyses will be conducted within a separate work package of the ICare project.

2.8. Sample size calculation

The study was designed with a recruitment phase of 2 years. Each participant has a fixed follow up duration of 12 months, i.e., after the end of the fixed follow up no further information about a patient's status will be acquired. We account for this mode of accrual and follow up by estimating the number of events necessary to show the assumed effect with at least 80% power and calculate the necessary number of participants directly by solving for N under the calculated number of events and the assumed event rates. Event rates are assumed to follow an exponential distribution and the dropout rate is assumed to be equal in both groups. For the purpose of sample size calculation for the planned time to event analysis, we assumed an expected rate of events (ED symptom improvement) after 8 months of 0.5 in the intervention group and of 0.3 in the waiting list group, based on published data on abstinence rates after outpatient treatment (e.g. Fairburn et al., 2009). To detect a 20% difference in event rates between the intervention group and the waiting list group, a sample size of $N = 193$ is sufficient. As the probability of study drop out is estimated to be 30% during a 12 month follow up, a total of $N = 275$ participants have to be randomized (completed baseline assessment). For the sample size calculation, a 2-stage adaptive group sequential design was planned according to Wang and Tsiatis (1987). The purpose of the interim analysis is a sample size recalculation based on the observed effect within the first stage of the trial. The sample size of the second stage will be calculated using the inverse normal method (Lehmacher and Wassmer, 1999) to maintain a conditional power of 80% in the second stage.

3. Discussion

Patients seeking help for mental health disorders often receive

access to specialized mental health care only after a significant period of delay. Internet-based interventions could help bridge the gap between seeking help and start of treatment.

The number of trials investigating Internet-based self-help for the treatment of mental disorders including BN, BED and OSFED is still small but is growing. Existing research has demonstrated that internet-based self-help can be a promising alternative to traditional cognitive behavioral therapy in a face-to-face setting (Dolemeyer et al., 2013). However, most of the evidence is based on trials with samples recruited from the general population and self-referred participants. Also, effects of internet-based self-help usually have been investigated as a stand-alone intervention. However, to date, little is known about the usefulness (feasibility, acceptability and effectiveness) of internet-based treatment interventions when offered in routine mental health care. In order to "determine the place for E-health in our health care service delivery systems" (Aardoom et al., 2016b) and to provide a reliable basis for the implementation of E-health interventions in the health care delivery system, we need to know whether Internet-based self-help in outpatient settings is as effective as in the general population. Outpatients (who have applied for face-to-face therapy) may respond differently to online treatment, and their motivation to engage in an online intervention may differ from that of other patients since they are expecting to be provided with subsequent face-to-face treatment anyway. We hope our study contributes to the limited body of knowledge in this field.

The current study protocol describes the first randomized controlled trial aiming to analyze the effects of an internet-based self-help intervention for women with BN, BED and OSFED on a waiting list for face-to-face outpatient treatment, conducted in an outpatient setting.

3.1.1. Strengths and challenges

A number of strengths and limitations of this study have to be taken into consideration. Strengths involve the randomized controlled study design and 12 month follow-up to assess the short- and longer-term effects of the intervention. The study intervention (everyBody Plus) has been evaluated in many previous studies with different populations and in different countries (Beintner et al., 2012) and proven to be effective for women with subclinical eating disorders (Jacobi et al., 2012; Saekow et al., 2015). A detailed statistical analysis plan has been set up and state-of-the-art methods will be used to deal with missing data. Also, a health-economic evaluation (cost-effectiveness) will be included. Furthermore, this study will be conducted in outpatient routine clinical practice under real life conditions using a pragmatic design. Patients will be recruited from existing waiting lists and start their face-to-face treatment whenever a time slot becomes available. The waiting time will not be artificially extended. Thus, results will also shed light on the feasibility of implementing online self-help to bridge waiting time for outpatients. Finally, because the intervention is delivered online, it is accessible 24/7 and can be accessed from any location allowing for a lot of flexibility to accommodate the user.

However, the pragmatic design also bears some challenges: time spent on the waiting list is variable, as is time spent in the online intervention until the start of the face-to-face treatment. Since we do not want to interfere with the routine processes in private practices or outpatient treatment centers, we will have to take into account a number of differences between cooperating recruitment partners and enrolled participants.

Another challenge could be the attitude of some psychotherapists regarding online interventions. Some may still be hesitant or reluctant to utilize online interventions in general or as part of a stepped-care approach of outpatient treatment delivery. Some psychotherapists believe that the psychological treatment cannot be adequately delivered via the internet, because of concerns that a therapeutic alliance cannot be established via such a 'cold' medium (Berger, 2016). Although there is research evidence that an alliance similar to that in face-to-face settings can be formed (Berger, 2016; Klasen et al., 2013), these concerns remain persistent. As at least half of the participants in this trial are recruited via cooperating psychotherapists (German site), this may pose a challenge for the recruitment process of the study.

Finally, adherence represents a major challenge in internet interventions in general. Poor adherence may be associated with a negative treatment outcome that can influence the patients' help-seeking behavior in the future (Beintner et al., 2014). To maintain adherence, we have therefore scheduled a number of e-mail reminders throughout this trial. In addition, measurement of intervention adherence is a main goal of all trials within the ICare project. A variety of adherence measures is defined and will be analyzed in a separate ICare work package.

4. Conclusion

This trial will be conducted as part of the ICare (Integrating Technology into Mental Health Care Delivery in Europe) project. The aim of ICare researchers from six European countries is to improve mental health care delivery in Europe and challenge traditional implementation barriers.

We expect the findings of this study to contribute to the body of knowledge on the effects, feasibility and acceptance of internet-based interventions in outpatient settings, as part of a stepped-care approach and to improve our knowledge on blending internet-based interventions with conventional treatment. If successfully implemented as a part of everyday routine, online interventions could be used to overcome the enormous gap in the health care delivery system and disburden patients and health care providers.

Trial status

Recruitment started in November 2016 and will continue through 31 May 2018 approximately. The first patient was enrolled in the study on 29 November 2016. Follow-up assessments for the remaining patients are expected to be completed by May 2019.

Competing interests

The authors declare that they have no competing interests.

Funding

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No 634757.

Ulrike Schmidt is supported by a Senior Investigator award from the National Institute for Health Research (NIHR) and receives salary support from the NIHR Biomedical Research Centre for Mental Health, South London and Maudsley NHS Foundation Trust and Institute of Psychiatry, Psychology and Neuroscience, King's College London. The views expressed herein are not those of NIHR or the NHS.

Author contributions

IB, PM and CJ designed the study. BV and DG contributed significantly to the study design. DG performed the sample size calculations and drafted the statistical design of the trial. BV wrote the first draft of the manuscript. All other authors contributed to critical revisions of the manuscript. All authors read and approved the final manuscript.

Acknowledgements

We would like to thank all participating psychotherapist and outpatient treatment centers for their support in the recruitment process.

The study will be part of the doctoral thesis of BV.

References

Aardoom, J.J., Dingemans, A.E., Spinhoven, P., Van Furth, E.F., 2013. Treating eating disorders over the internet: a systematic review and future research directions. Int. J. Eat. Disord. 46 (6), 539–552. http://dx.doi.org/10.1002/eat.22135.

Aardoom, J.J., Dingemans, A.E., Spinhoven, P., van Ginkel, J.R., de Rooij, M., van Furth, E.F., 2016a. Web-based fully automated self-help with different levels of therapist support for individuals with eating disorder symptoms: a randomized controlled trial. J. Med. Internet Res. 18 (6), e159. http://dx.doi.org/10.2196/jmir.5709.

Aardoom, J.J., Dingemans, A.E., Van Furth, E.F., 2016b. E-health interventions for eating disorders: emerging findings, issues, and opportunities. Curr. Psychiatry Rep. 18 (4), 42. http://dx.doi.org/10.1007/s11920-016-0673-6.

Ágh, T., Kovács, G., Pawaskar, M., Supina, D., Inotai, A., Vokó, Z., 2015. Epidemiology, health-related quality of life and economic burden of binge eating disorder: a systematic literature review. Eat. Weight Disord. 20 (1), 1–12. http://dx.doi.org/10.1007/s40519-014-0173-9.

Agras, W.S., 2001. The consequences and costs of the eating disorders. Psychiatr. Clin. N. Am. 24 (2), 371–379. http://dx.doi.org/10.1016/S0193-953X(05)70232-X.

American Psychiatric Association, 2013. Diagnostic and Statistical Manual of Mental Disorders, 5th ed. Author, Washington, DC.

Bauer, S., Moessner, M., 2013. Harnessing the power of technology for the treatment and prevention of eating disorders. Int. J. Eat. Disord. 46 (5), 508–515. http://dx.doi.org/10.1002/eat.22109.

Becker, A.E., Hadley Arrindell, A., Perloe, A., Fay, K., Striegel-Moore, R.H., 2010. A qualitative study of perceived social barriers to care for eating disorders: perspectives from ethnically diverse health care consumers. Int. J. Eat. Disord. 43 (7), 633–647. http://dx.doi.org/10.1002/eat.20755.

Beecham, J., Knapp, M., 2001. Costing psychiatric interventions. In: Thornicroft, G. (Ed.), Measuring Mental Health Needs, 2 ed. Royal College of Psychiatrists, London, pp. 200–224.

Beintner, I., Jacobi, C., Taylor, C.B., 2012. Effects of an internet-based prevention programme for eating disorders in the USA and Germany — a meta-analytic review. Eur. Eat. Disord. Rev. 20 (1), 1–8. http://dx.doi.org/10.1002/erv.1130.

Beintner, I., Jacobi, C., Schmidt, U.H., 2014. Participation and outcome in manualized self-help for bulimia nervosa and binge eating disorder — a systematic review and metaregression analysis. Clin. Psychol. Rev. 34 (2), 158–176. http://dx.doi.org/10.1016/j.cpr.2014.01.003.

Berger, T., 2016. The therapeutic alliance in internet interventions: a narrative review and suggestions for future research. Psychother. Res. 1–14. http://dx.doi.org/10.1080/10503307.2015.1119908.

BPtK, 2011. BPtK-Studie zu Wartezeiten in der ambulanten psychotherapeutischen Versorgung. Umfrage der Landespsychotherapeutenkammern und der BPtK. Bundespsychotherapeutenkammer, Berlin.

Burket, R.C., Schramm, L.L., 1995. Therapists' attitudes about treating patients with eating disorders. South. Med. J. 88 (8), 813–818.

Bush, K., Kivlahan, D.R., McDonell, M.B., Fihn, S.D., Bradley, K.A., 1998. The audit alcohol consumption questions (audit-c): an effective brief screening test for problem drinking. Arch. Intern. Med. 158 (16), 1789–1795. http://dx.doi.org/10.1001/archinte.158.16.1789.

Calzo, J.P., Horton, N.J., Sonneville, K.R., Swanson, S.A., Crosby, R.D., Micali, N., ... Field, A.E., 2016. Male eating disorder symptom patterns and health correlates from 13 to 26 years of age. J. Am. Acad. Child Adolesc. Psychiatry 55 (8), 693–700.e692. http://dx.doi.org/10.1016/j.jaac.2016.05.011.

Carrard, I., Crépin, C., Rouget, P., Lam, T., Golay, A., Van der Linden, M., 2011a. Randomised controlled trial of a guided self-help treatment on the Internet for binge eating disorder. Behav. Res. Ther. 49 (8), 482–491. http://dx.doi.org/10.1016/j.brat.2011.05.004.

Carrard, I., Crepin, C., Rouget, P., Lam, T., van der Linden, M., Alain, G., 2011b. Acceptance and efficacy of a guided internet self-help treatment program for obese patients with binge eating disorder. Clin. Pract. Epidemiol. Ment. Health 7, 8–18.

Carrard, I., Fernandez-Aranda, F., Lam, T., Nevonen, L., Liwowsky, I., Volkart, A.C., ... Norring, C., 2011c. Evaluation of a guided internet self-treatment programme for bulimia nervosa in several European countries. Eur. Eat. Disord. Rev. 19 (2), 138–149. http://dx.doi.org/10.1002/erv.1043.

Crow, S.J., Agras, W.S., Halmi, K.A., Fairburn, C.G., Mitchell, J.E., Nyman, J.A., 2013. A cost effectiveness analysis of stepped care treatment for bulimia nervosa. Int. J. Eat. Disord. 46 (4), 302–307. http://dx.doi.org/10.1002/eat.22087.

DeJong, H., Oldershaw, A., Sternheim, L., Samarawickrema, N., Kenyon, M.D., Broadbent, H., ... Schmidt, U., 2013. Quality of life in anorexia nervosa, bulimia nervosa and eating disorder not-otherwise-specified. J. Eat. Disord. 1 (1), 43. http://dx.doi.org/10.1186/2050-2974-1-43.

Dolemeyer, R., Tietjen, A., Kersting, A., Wagner, B., 2013. Internet-based interventions for eating disorders in adults: a systematic review. BMC Psychiatry 13 (1), 207.

Evans, E.J., Hay, P.J., Mond, J., Paxton, S.J., Quirk, F., Rodgers, B., ... Sawoniewska, M.A., 2011. Barriers to help-seeking in young women with eating disorders: a qualitative exploration in a longitudinal community survey. Eat. Disord. 19 (3), 270–285. http://dx.doi.org/10.1080/10640266.2011.566152.

Eysenbach, G., Consort-Ehealth Group, 2011. CONSORT-EHEALTH: improving and standardizing evaluation reports of web-based and mobile health interventions. J. Med. Internet Res. 13 (4), e126. http://dx.doi.org/10.2196/jmir.1923.

Fairburn, C.G., Beglin, S.J., 2008. Eating Disorder Examination Questionnaire. In: Fairburn, C.G. (Ed.), Cognitive Behavior Therapy and Eating Disorders. Guildford Press, New York.

Fairburn, C.G., Patel, V., 2014. The global dissemination of psychological treatments: a road map for research and practice. Am. J. Psychiatr. 171 (5), 495–498. http://dx.doi.org/10.1176/appi.ajp.2013.13111546.

Fairburn, C.G., Cooper, Z., Doll, H.A., O'Connor, M.E., Bohn, K., Hawker, D.M., ... Palmer, R.L., 2009. Transdiagnostic cognitive-behavioral therapy for patients with eating disorders: a two-site trial with 60-week follow-up. Am. J. Psychiatry 166 (3), 311–319.

Ferring, D., Filipp, S.-H., 1996. Messung des Selbstwertgefühls: Befunde zu Reliabilität, Validität und Stabilität der Rosenberg-Skala. Diagnostica 42, 284–292.

Grund, K., 2003. Validierung der Weight Concerns Scale zur Erfassung von Essstörungen (Diploma Thesis, Unpublished). Universität Trier, Trier.

Hatcher, R.L., Gillaspy, J.A., 2006. Development and validation of a revised short version of the working alliance inventory. Psychother. Res. 16 (1), 12–25. http://dx.doi.org/10.1080/10503300500352500.

Herbert, B.M., Blechert, J., Hautzinger, M., Matthias, E., Herbert, C., 2013. Intuitive eating is associated with interoceptive sensitivity. Effects on body mass index. Appetite 70, 22–30. http://dx.doi.org/10.1016/j.appet.2013.06.082.

Hilbert, A., Tuschen-Caffier, B., 2006. Eating Disorder Examination-Questionnaire: Deutschsprachige Übersetzung. Verlag für Psychotherapie, Münster.

Hoek, H.W., 2006. Incidence, prevalence and mortality of anorexia nervosa and other eating disorders. Curr. Opin. Psychiatry 19 (4), 389–394. http://dx.doi.org/10.1097/01.yco.0000228759.95237.78.

Hötzel, K., von Brachel, R., Schmidt, U., Rieger, E., Kosfelder, J., Hechler, T., ... Vocks, S., 2014. An internet-based program to enhance motivation to change in females with symptoms of an eating disorder: a randomized controlled trial. Psychol. Med. 44 (9), 1947–1963. http://dx.doi.org/10.1017/s0033291713002481.

Jacobi, C., Volker, U., Trockel, M.T., Taylor, C.B., 2012. Effects of an Internet-based intervention for subthreshold eating disorders: a randomized controlled trial. Behav. Res. Ther. 50 (2), 93–99. http://dx.doi.org/10.1016/j.brat.2011.09.013.

Jacobi, F., Höfler, M., Siegert, J., Mack, S., Gerschler, A., Scholl, L., ... Wittchen, H.-U., 2014. Twelve-month prevalence, comorbidity and correlates of mental disorders in Germany: the Mental Health Module of the German Health Interview and Examination Survey for Adults (DEGS1-MH). Int. J. Methods Psychiatr. Res. 23 (3), 304–319. http://dx.doi.org/10.1002/mpr.1439.

Kenter, R., Cuijpers, P., Beekman, A., van Straten, A., 2016. Effectiveness of a web-based guided self-help intervention for outpatients with a depressive disorder: short-term results from a randomized controlled trial. J. Med. Internet Res. 18 (3), e80. http://dx.doi.org/10.2196/jmir.4861.

Killen, J.D., Taylor, C.B., Hayward, C., Haydel, K.F., Wilson, D.M., Hammer, L., ... Strachowski, D., 1996. Weight concerns influence the development of eating disorders: a 4-year prospective study. J. Consult. Clin. Psychol. 64 (5), 936–940. http://dx.doi.org/10.1037/0022-006x.64.5.936.

Klasen, M., Knaevelsrud, C., Böttche, M., 2013. Die therapeutische Beziehung in internetbasierten Therapieverfahren. Nervenarzt 84 (7), 823–831. http://dx.doi.org/10.1007/s00115-012-3659-6.

Knapp, M., McDaid, D., Mossialos, E., Thornicroft, G., 2007. Mental Health Policy and Practice Across Europe: The Future Direction of Mental Health Care. Open University Press, Maidenhead, UK.

Kohn, R., Saxena, S., Levav, I., Saraceno, B., 2004. The treatment gap in mental health care. Bull. World Health Organ. 82 (11), 858–866.

Kok, R.N., van Straten, A., Beekman, A.T.F., Cuijpers, P., 2014. Short-term effectiveness of web-based guided self-help for phobic outpatients: randomized controlled trial. J. Med. Internet Res. 16 (9), e226. http://dx.doi.org/10.2196/jmir.3429.

Krampen, G., 2002. Stundenbogen für die Allgemeine und Differentielle Einzelpsychotherapie (STEP). Manual. Hogrefe, Göttingen.

Le, L.K., Barendregt, J.J., Hay, P., Mihalopoulos, C., 2017. Prevention of eating disorders: a systematic review and meta-analysis. Clin. Psychol. Rev. 53, 46–58. http://dx.doi.org/10.1016/j.cpr.2017.02.001.

Lehmacher, W., Wassmer, G., 1999. Adaptive sample size calculations in group sequential trials. Biometrics 55 (4), 1286–1290. http://dx.doi.org/10.1111/j.0006-341X.1999.01286.x.

Loucas, C.E., Fairburn, C.G., Whittington, C., Pennant, M.E., Stockton, S., Kendall, T., 2014. E-therapy in the treatment and prevention of eating disorders: a systematic review and meta-analysis. Behav. Res. Ther. 63, 122–131. http://dx.doi.org/10.1016/j.brat.2014.09.011.

Löwe, B., Kroenke, K., Herzog, W., Gräfe, K., 2004. Measuring depression outcome with a brief self-report instrument: sensitivity to change of the Patient Health Questionnaire (PHQ-9). J. Affect. Disord. 81 (1), 61–66. http://dx.doi.org/10.1016/S0165-0327(03)00198-8.

Melioli, T., Bauer, S., Franko, D.L., Moessner, M., Ozer, F., Chabrol, H., Rodgers, R.F., 2016. Reducing eating disorder symptoms and risk factors using the internet: a meta-analytic review. Int. J. Eat. Disord. 49 (1), 19–31. http://dx.doi.org/10.1002/eat.22477.

Mind, 2010. We need to talk. Getting the right therapy at the right time. Retrieved June 1, 2017, from. https://www.mind.org.uk/media/280583/We-Need-to-Talk-getting-the-right-therapy-at-the-right-time.pdf.

Mind, 2013. We still need to talk. A report on access to talking therapies. Retrieved June, 1, 2017, from. http://www.mind.org.uk/media/494424/we-still-need-to-talk_report.pdf.

Mitchell, J.E., Agras, S., Wonderlich, S., 2007. Treatment of bulimia nervosa: where are we and where are we going? Int. J. Eat. Disord. 40 (2), 95–101. http://dx.doi.org/10.1002/eat.20343.

Mitchell, J.E., Agras, S., Crow, S., Halmi, K., Fairburn, C.G., Bryson, S., Kraemer, H., 2011. Stepped care and cognitive behavioural therapy for bulimia nervosa: randomised trial. Br. J. Psychiatry 198 (5), 391–397. http://dx.doi.org/10.1192/bjp.bp.110.082172.

Moher, D., Schulz, K.F., Altman, D.G., 2001. The CONSORT statement: revised recommendations for improving the quality of reports of parallel-group randomized trials. Ann. Intern. Med. 134 (8), 657–662.

Moher, D., Hopewell, S., Schulz, K.F., Montori, V., Gotzsche, P.C., Devereaux, P.J., ... Altman, D.G., 2010. CONSORT 2010 explanation and elaboration: updated guidelines for reporting parallel group randomised trials. BMJ 340, c869. http://dx.doi.org/10.1136/bmj.c869.

National Institute for Health and Care Excellence (NICE), 2017. Eating Disorders: Recognition and Treatment (Nice guideline NG69). Retrieved 05.07.2017, 2017, from. https://www.nice.org.uk/guidance/ng69/.

Richardson, J., Iezzi, A., Khan, M.A., Maxwell, A., 2014. Validity and reliability of the assessment of quality of life (AQoL)-8D multi-attribute utility instrument. Patient Patient Cent. Outcomes Res. 7 (1), 85–96. http://dx.doi.org/10.1007/s40271-013-0036-x.

Rosenberg, M., 1965. Society and the Adolescent Self-image. Princeton University Press, Princeton.

Ruwaard, J., Lange, A., Broeksteeg, J., Renteria-Agirre, A., Schrieken, B., Dolan, C.V., Emmelkamp, P., 2013. Online cognitive–behavioural treatment of bulimic symptoms: a randomized controlled trial. Clin. Psychol. Psychother. 20 (4), 308–318. http://dx.doi.org/10.1002/cpp.1767.

Saekow, J., Jones, M., Gibbs, E., Jacobi, C., Fitzsimmons-Craft, E.E., Wilfley, D., Barr Taylor, C., 2015. StudentBodies-eating disorders: a randomized controlled trial of a coached online intervention for subclinical eating disorders. Internet Interventions 2 (4), 419–428. http://dx.doi.org/10.1016/j.invent.2015.10.004.

Sanchez-Ortiz, V.C., Munro, C., Stahl, D., House, J., Startup, H., Treasure, J., ... Schmidt, U., 2011. A randomized controlled trial of internet-based cognitive-behavioural therapy for bulimia nervosa or related disorders in a student population. Psychol. Med. 41 (2), 407–417. http://dx.doi.org/10.1017/s0033291710000711.

Schlegl, S., Bürger, C., Schmidt, L., Herbst, N., Voderholzer, U., 2015. The potential of technology-based psychological interventions for anorexia and bulimia nervosa: a systematic review and recommendations for future research. J. Med. Internet Res. 17 (3), e85. http://dx.doi.org/10.2196/jmir.3554.

Spitzer, R.L., Kroenke, K., Williams, J.W., Löwe, B., 2006. A brief measure for assessing generalized anxiety disorder: the gad-7. Arch. Intern. Med. 166 (10), 1092–1097. http://dx.doi.org/10.1001/archinte.166.10.1092.

Steinhausen, H.-C., Weber, S., 2009. The outcome of bulimia nervosa: findings from one-quarter century of research. Am. J. Psychiatr. 166 (12), 1331–1341. http://dx.doi.org/10.1176/appi.ajp.2009.09040582.

ter Huurne, E.D., de Haan, H.A., Postel, M.G., van der Palen, J., VanDerNagel, J.E., DeJong, C.A., 2015. Web-based cognitive behavioral therapy for female patients with eating disorders: randomized controlled trial. J. Med. Internet Res. 17 (6), e152. http://dx.doi.org/10.2196/jmir.3946.

The Centre for Economic Performance's Mental Health Policy Group, 2012. How Mental Illness Loses Out on the NHS: Centre for Economic Performance. The London School of Economics and Political Science.

Tylka, T.L., 2006. Development and psychometric evaluation of a measure of intuitive eating. J. Couns. Psychol. 53 (2), 226–240. http://dx.doi.org/10.1037/0022-0167.53.2.226.

Vocks, S., Tuschen-Caffer, B., Pietrowsky, R., Rustenbach, S.J., Kersting, A., Herpertz, S., 2010. Meta-analysis of the effectiveness of psychological and pharmacological treatments for binge eating disorder. Int. J. Eat. Disord. 43 (3), 205–217. http://dx.doi.org/10.1002/eat.20696.

Wang, S.K., Tsiatis, A.A., 1987. Approximately optimal one-parameter boundaries for group sequential trials. Biometrics 43 (1), 193–199. http://dx.doi.org/10.2307/2531959.

Wilmers, F., Munder, T., Leonhart, R., Herzog, T., Plassmann, R., Barth, J., Linster, H.W., 2008. Die deutschsprachige Version des Working Alliance Inventory–short revised (WAI-SR). Ein schulenübergreifendes, ökonomisches und empirisch validiertes Instrument zur Erfassung der therapeutischen Allianz. Klinische Diagnostik und Evaluation 1 (3), 343–358.

Wilson, G.T., Shafran, R., 2005. Eating disorders guidelines from NICE. Lancet 365 (9453), 79–81. http://dx.doi.org/10.1016/S0140-6736(04)17669-1.

Wurst, F.M., Rumpf, H.-J., Skipper, G.E., Allen, J.P., Kunz, I., Beschoner, P., Thon, N., 2013. Estimating the prevalence of drinking problems among physicians. Gen. Hosp. Psychiatry 35 (5), 561–564. http://dx.doi.org/10.1016/j.genhosppsych.2013.04.018.